OCT 2 6 2001

K012809 (P.1 of 3)

PREMARKET NOTIFICATION 510(K SAFETY AND EFFECTIVENESS SUMMARY

SurgASSIST™ Right Angle Linear Cutter Digital Loading Unit™ (DLU)

In Accordance with 21 CFR section 807.92, Power Medical Interventions, Inc., is submitting the following Safety and Effectiveness Summary.

1) Submitter Information:

Power Medical Interventions, Inc.
4 B East Bridge St.
New Hope, PA 18938 USA
215-862-4450
215-862-1009 FAX

Applicant: Laurence A. Potter

Date of Notification: August 17, 2001

2) Name of Device:

Trade Name: SurgASSIST™ System
Right Angle Linear Cutter
Digital Loading Unit™

Common Name: Linear Cutter with Implantable Staples

Classification Name: Staple, Implantable, GDW, Stapler, GAG

3) Predicate Devices: LINEAR CUTTERS / STAPLING INSTRUMENTS

A. SurgASSIST™ System, Circular Stapler Digital Loading Unit. Power Medical Interventions, Inc., New Hope, PA. REF CS21, CS25, CS29, CS33. (K003277)

B. Proximate® Linear Cutter and Four Row with Safety Lock-Out. Ethicon Endo-Surgery, Inc., Cincinnati, Ohio. REF TLC55 (K890841)

C. United States Surgical Powered Endoscopic GIA Stapler. United States Surgical Corp., Norwalk, CT. (K913802).

4) Device Description:

The SurgASSIST™ System with Right Angle Linear Cutter Digital Loading Unit™ (DLU) is a cutter/stapler component addition to a previously cleared device, K003277, SurgASSIST™ System with Circular Stapler Disposable Loading Unit. This Notification offers an additional style of cutting/stapling configuration, specifically, a right angle linear cutter/stapler of 45mm in length. The computer mediated, powered steering, tissue cutting and stapling of the Right Angle Linear Cutter is utilizing the identical technology and system approach which the previously cleared device currently utilizes.

The technological features of the SurgASSIST™ System with Right Angle 45mm Linear Cutter are identical to that of the predicate device, K003277.

- A steerable FlexShaft that serves as the interface between the Digital Loading Unit™ (DLU) and the Power Console and provides the means of insertion of the DLU. The FlexShaft is steerable for surgical positioning of the DLU for access and visualization.

- A hand held Remote Control Unit that contains pushbuttons that actuate steering, extension and retraction of the anvil, stapling, and cutting.

- Right Angle Linear Cutter Digital Loading Unit (DLU) that contains implantable staples that form in a double staggered linear row of staples and a steel knife blade which transects the tissue between the two rows of formed staples. The Cutter is designed to angle 90° from the center line of the FlexShaft, permitting access to tissue which may not normally be accessed via current stapling techniques and hardware. The Right Angle Linear Cutter DLU is offered currently in a 45mm length size, in non-reloadable configuration.

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5) Indications For Use

The SurgASSIST™ System with Right Angle Linear Cutter DLU has applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.

6) Comparison to Predicate Devices

1. SurgASSIST™ System, Circular Stapler Digital Loading Unit. Power Medical Interventions, Inc., New Hope, PA. (K003277)

2. Proximate® Linear Cutter and Four Row with Safety Lock-Out. Ethicon Endo-Surgery, Inc., Cincinnati, Ohio. REF TLC55 (K890841)

3. United States Surgical Powered Endoscopic GIA Stapler. United States Surgical, Norwalk, CT. USA (K913802)

Substantial equivalence includes the predicate SurgASSIST™ System with Circular Staple Disposable Loading Unit literature including descriptions, specifications, identification of standard components, and identification of tissue contact materials.

Substantial Equivalence for this Notification also includes a preclinical study in porcine subjects to assess the SurgASSIST™ System Right Angle Linear Cutter DLU against a predicate device, Ethicon's Proximate® Linear Cutter with Safety Lock-Out (TLC55), having comparable intended use. Additional Laboratory Bench Testing of the subject device against the Proximate predicate is also defined within this Notification and summarized as equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2001

Mr. Laurence A. Potter
Vice President
Regulatory Affairs & Quality Assurance
Power Medical Interventions, Inc.
4 B East Bridge Street
New Hope, Pennsylvania 18938

Re: K012809
Trade/Device Name: SurgASSIST™ System Right Angle Linear Cutter Digital Loading Unit™
Regulation Number: 878.4750
Regulation Name: Implantable Staple
Regulatory Class: II
Product Code: GDW
Dated: August 17, 2001
Received: August 22, 2001

Dear Mr. Potter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D

STATEMENT OF INTENDED USE

Power Medical Interventions, Inc.

510(k) No. K 012809

Device Name:

SurgASSIST™ System
Right Angle Linear Cutter
Digital Loading Unit™

INDICATIONS FOR USE:

The SurgASSIST™ System with Right Angle Linear Cutter DLU has applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.

(PLEASE DO NOT WRITE BELOW THIS LINE – (CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use X (per 21 CFR 801.109)

Over-The-Counter Use _____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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510(k) Number K012809